

DEC 16 2011

510(k) Summary
Twister™ Side-Firing Fiber Optic Delivery System

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Biolitec Medical Devices, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
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Contact Person: Harry Hayes, Ph.D. – Regulatory Consultant
Date prepared: October 5, 2011

Name of Device and Name/Address of Sponsor
Twister™ Side-Firing Fiber Optic Delivery System
Biolitec Medical Devices, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name
Surgical laser & accessories

Predicate Devices
Megabeam® Lateral/ Side Fire Fiber Optic Delivery System, (K940008, K941909, K943444, K943526, K943527 and K060050)

Intended Use/Indication for Use
The Twister™ Side-Fire Fiber Optic Delivery System is a delivery accessory used to deliver optical energy and is indicated for use in general surgical applications in combination with any SMA-compatible laser system also indicated for the same applications. It is indicated for use in hemostasis, ablation and vaporization of soft or fibrous tissue in any surgical discipline in contact or non-contact mode with a compatible laser marketed for the desired application. The system can be used with or without a standard viewing scope. It can be inserted through the working channel of a cystoscope, urethroscope, or any other viewing scope.

Technological Characteristics
The Biolitec Medical Devices, Inc. Twister™ Side-Fire Fiber Optic Delivery System contains equivalent components and identical patient-contact materials as the cleared Biolitec Inc. Megabeam Lateral/ Side Fire Fiber Optic Delivery Systems.

Performance Data

Since the performance of the Twister™ Side-Fire Fiber Optic Delivery System is well established and documented on soft tissue no performance testing is being specifically included in this submission.

Substantial Equivalence

The Twister™ Side-Fire Fiber Optic Delivery System is as safe and effective for these Indications for Use as the Biolitec Inc MegaBeam® Lateral/ Side Fire Fiber Optic Delivery System. Thus, the Twister™ Side-Fire Fiber Optic Delivery System for Biolitec Medical Devices, Inc. is substantially equivalent to its predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2011

Biolitec Medical Device, Incorporated
% Genmarhay, BDA
Harry Hayes, Ph.D.
Regulatory Consultant
1349 Main Road
Grandville, Massachusetts 01034

Re: K112987

Trade/Device Name: Twister™ Side-Firing Optic Delivery System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: October 5, 2011

Received: October 6, 2011

Dear Dr. Hayes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

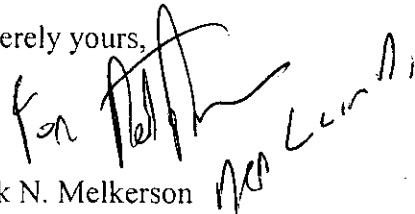
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name and title.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112987

Device Name: Twister™ Side-Firing Fiber Optic Delivery System

Indications for Use: The Twister™ Side-Firing Fiber Optic Delivery System is intended for use as a fiber optic delivery system in conjunction with any surgical laser with SMA 905 compatible connector. The Twister™ Side-Firing Fiber Optic Delivery System is indicated for hemostasis, ablation and vaporization of soft or fibrous tissue in any surgical discipline in contact or non contact mode with a compatible laser marketed for the desired application. The system can be used with or without a standard viewing scope. It can be inserted through the working channel of a cystoscope, urethroscope, or any other viewing scope.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

N. A. Ogden for mmm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112987